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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,990	11/21/2003	Horst Heirler	028622-0125	8166

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EXAMINER	
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ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
06/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Advisory Action Before the Filing of an Appeal Brief	**Application No.** 10/717,990	**Applicant(s)** HEIRLER, HORST	
	Examiner Leslie A. Royds	**Art Unit** 1614	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 15 May 2008 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:
   a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.
   b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

   Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
   (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);
   (b) ☐ They raise the issue of new matter (see NOTE below);
   (c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
   (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____. (See 37 CFR 1.116 and 41.33(a)).
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
   The status of the claim(s) is (or will be) as follows:
   Claim(s) allowed: _____.
   Claim(s) objected to: _____.
   Claim(s) rejected: *1,3-6 and 8-20*.
   Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
12. ☐ Note the attached Information *Disclosure Statement*(s). (PTO/SB/08) Paper No(s). _____
13. ☐ Other: _____.

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

Continuation of 11. does NOT place the application in condition for allowance because:

Applicant's request for reconsideration with regard to the present rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) in light of the remarks presented in the after-final submission dated May 15, 2008 has been made. Applicant traverses the rejections of the following grounds:

(1) Regarding the rejection under 35 U.S.C. 102(b), Applicant states that the method instantly claimed requires the administration of a composition, which Applicant asserts is prepared outside of the body and, therefore, is not anticipated by the fact that the alpha-linolenic acid of Alexander must be metabolized in the stomach to be converted to eicosapentaen and/or docosahexaen acid. Applicant additionally asserts that only 2-7%of linoleic acid is converted into long-chain omega-3 fatty acids and, therefore, fails to meet the claimed amount of "an amount sufficient to regulate and normalize fat metabolism in the patient being treated".

(2) Regarding the rejection of claims 1, 3, 6, 9 and 11-19 under 35 U.S.C. 103(a), Applicant states that the references to Alexander and Brenna fail to teach or suggest the invention of claims 1, 3 and 6 as discussed above and Harries fails to disclose or suggest the claimed invention.

(3) Regarding the rejection of claims 1, 3-6, 8-10 and 20, Applicant alleges that the statement in Madigan that linoleic acid diet may not be the best option for people with type 2 diabetes actually means that linoleic acid is totally unsuitable for the treatment of type 2 diabetes and relies upon the fact that Madigan concludes an oleic-acid rich diet versus a linoleic acid rich diet may reduce the risk of arteriosclerosis in order to conclude that one of skill in the art would not be motivated to administer a linoleic acid rich diet to a type 2 diabetic patient. Applicant also asserts that, though Heine may show that a linoleic-enriched diet in patients with NIDD causes a less atherogenic lipoprotein profile, the reference clearly teaches that linoleic acid does not show a positive effect on glycemic control and carbohydrate tolerance.

Applicant's traversal has been fully and carefully considered, but fails to be persuasive for the following reasons:

(1) Firstly, Applicant has failed to provide any indication in the specification or claims as originally filed that the instantly claimed composition must be one that is prepared outside of the body. Accordingly, the assertion that the composition suggested by the Examiner does not meet the instant claims because one of the elements must be metabolized in the stomach to meet one of the instantly claimed elements is clearly not persuasive in this regard because Applicant is attempting to demonstrate patentable distinction over a limitation that is very conspicuously not claimed. Moreover, note that the case law upon which Applicant relies in support of this argument employed the phrase "medicinal preparation", which is not what is used in the instant claims. Applicant has simply claimed "a composition" and has failed to provide any limiting specifics about how it must be made to meet the instant claims. As a result, the fact that part of the composition may be supplied upon metabolism in the stomach is clearly not excluded from the instant claims. Secondly, Applicant appears to be of the persuasion that, since only 2-7% of linoleic acid is converted into long-chain omega-3 fatty acids, this amount fails to meet the instantly claimed amount sufficient to regulate and normalize fat metabolism in the patient to be treated. However, it is noted that Applicant has failed to explicitly define the amount of eicosapentaen and/or docosahexaen acid that is effective to regulate and normalize fat metabolism in the instant specification. Accordingly, nothing in the specification defines the degree of the amount sufficient to achieve the claimed effect such that the actual amount of the prior art is clearly excluded. In view of these facts and further absent any clear showing that the amount obtained from metabolic conversion is insufficient to achieve the claimed function, such remarks are unpersuasive.

(2) Applicant incorporates by reference the same remarks as set forth with regard to the instant rejection under 102(b). Accordingly, the Examiner hereby incorporates the same response as set forth under item (1) in response. For brevity, such remarks will not be repeated herein so as not to burden the record. Furthermore, consideration of Harries alone as Applicant has done is unpersuasive because Harries was used in combination with the cited reference to Alexander et al. and Brenna et al. and, therefore, must be considered in combination, not individually. Accordingly, the assertion that Harries alone fails to teach or suggest the claimed invention is unpersuasive because it was the combination of Alexander, Brenna and Harries together that assertedly teaches the claimed invention.

(3) Firstly, Applicant's attempt to conclude from what is disclosed in Madigan that a linoleic acid diet is totally unsuitable for a type 2 diabetic patient is again unpersuasive. Applicant is drawing an extreme conclusion from what is disclosed without considering the disclosure in the context in which it is written. Once again, Applicant is reminded that Madigan et al. disclose a linoleic-enriched diet as "not the best option", but does not completely discount its use by stating, as Applicant has alleged, that it is, in fact, UNSUITABLE for a type 2 diabetic. Simply put, the fact that a linoleic-enriched diet may be a non-preferred manner for treating diabetic patients does not constitute a teaching away from its use (preferred embodiments do not constitute a teaching away from a non-preferred embodiment; see MPEP 2123). Secondly, Heine et al. clearly supports the conclusion that, despite its lack of effect in providing glycemic control and/or carbohydrate tolerance, use of a linoleic acid-enriched diet in a diabetic patient does, in fact, provide at least some reduction in the atherogenic lipoprotein profile. Again, given these facts, it is maintained that one of ordinary skill in the art would have been motivated to combine a greater amount of linoleic acid (than what is provided for in Alexander et al.) with an even higher proportion of oleic acid because each of linoleic acid and oleic acid were well known in the art to provide some atherosclerotic protection (of which atherosclerosis is a known and potentially deadly complication of diabetes) by reducing serum lipoproteins. Further, since oleic acid was known to be more effective in this respect than linoleic acid, it again logically follows that the artisan would have been motivated to use an even greater amount of oleic acid than linoleic acid to provide the atherosclerotic protecting effects while providing improved diabetic glycemic control.

For these reasons presented supra, and those previously made of record in the final rejection dated January 15, 2008, rejection of claims 1, 3-6 and 8-20 remains proper and is maintained.